RESEARCH PROFESSIONALS NETWORK

January 2025 Workshop

Unlocking Success: Keys to Operationalizing a protocol

Presented by:
Linda Wozniak, BA - MUSC Program Manager I - Pediatric Research Group
&
Emilie Schmidt, BS, MS - UF Research Regulatory Analyst III & IRB Educator

1

Introductions

Linda Wozniak, BA - MUSC - Program Manager I
Pediatric Research Group

&

Emilie Schmidt, BS, MS - UF Research Regulatory Analyst III & IRB Educator

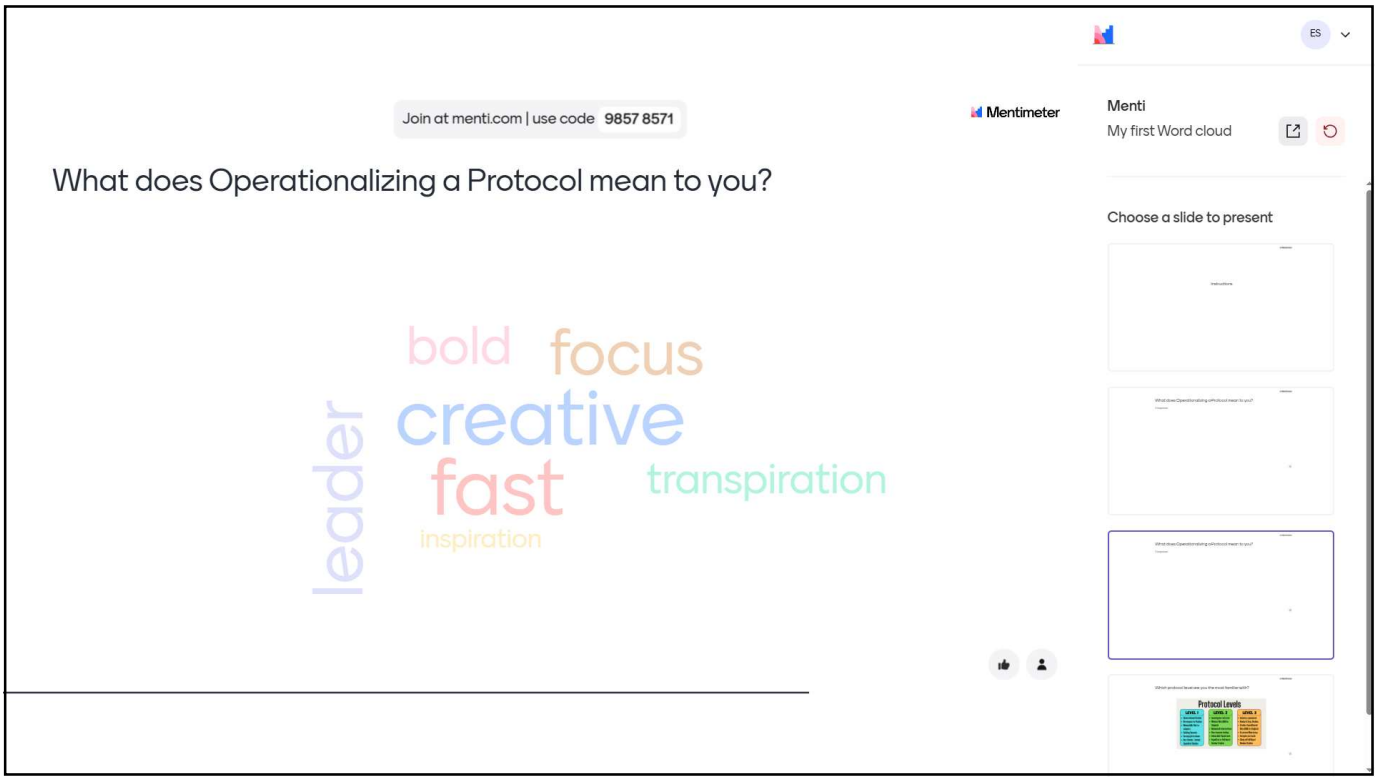
2

3

Workshop Agenda

- Operationalizing a Protocol - Definition
- Protocol Levels
- 6 Specific Categories of Focus
- Review of W6 - Who/What/When/Where/Why/How
- General Good Practice - Sharing Tips and Tricks
- Workshop Group Case-Study (No Breakouts - all together!) - Whiteboard
- Key Takeaways & Resources

4



5

Operationalizing a Protocol - Our Definition

- The Process of interpreting a protocol into actionable items to successfully conduct a study
- Being able to anticipate/predict the needs of your study
  - Example #1 – Long PK days – Do we need to pull in afterhours staff? Is there building access after hours?
  - Example #2 – Serial vitals measurements – do we need to buy the equipment (BP cuff, scale, etc…)?
  - Example #3 – physical exams involved – do we have someone qualified to conduct these assessments?

5

6

Definition of Protocol “Levels” - Level 1

Observational studies or retrospective chart/data reviews

- Risk: Minimal or no risk to participants
- Data Source: Existing records or data sets
- Primary Focus: Observing outcomes without intervening
- Approvals Needed: Often requires ethical approval, possibly waiver of consent
- Examples: Epidemiological studies, medical chart reviews, database analyses

7

Definition of Protocol “Levels” - Level 2

Investigator Initiated/Minimal Risk/Interventional

- Risk: Minimal risk interventions (e.g., behavioral modifications, surveys)
- Intervention: Direct interaction or intervention with participants
- Regulation: Often requires IRB/ethics committee approval
- Study Design: Pilot studies, feasibility studies, controlled trials with minimal intervention
- Examples: Lifestyle intervention trials, survey-based studies, low-risk drug trials

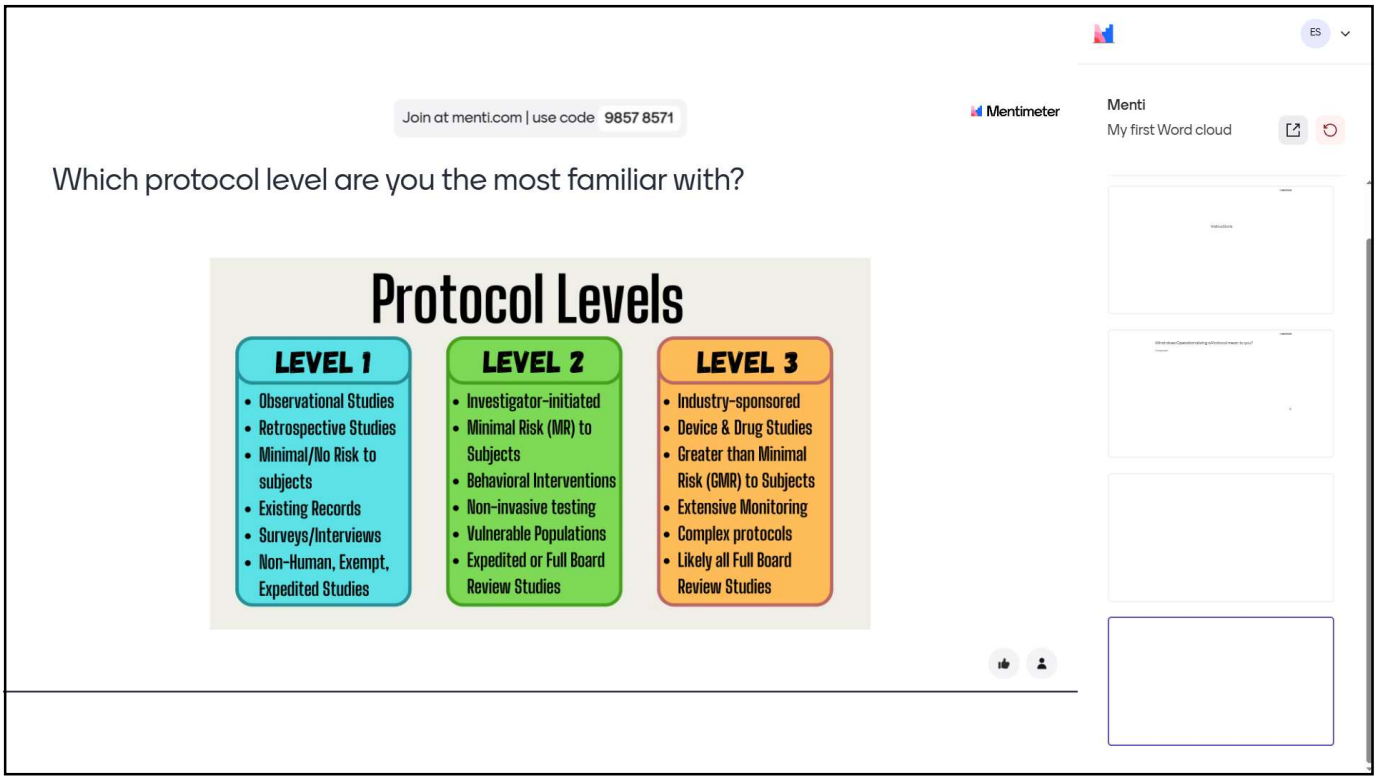
8

Definition of Protocol "Levels" - Level 3

Industry Sponsored/Investigational Product/Device

- Risk: Higher risk profile involving novel drugs/devices
- Regulation: Compliance with regulatory authorities (e.g., FDA, EMA)
- Monitoring: Extensive monitoring and oversight (e.g., Data Safety Monitoring Boards)
- Study Design: Complex protocols, often multi-site, randomized controlled trials
- Examples: Phase I-III drug trials, new medical device testing, combination therapy studies

9



10

Categories of focus when reviewing protocols

- SOE & Study Procedures (with timing)
- Staffing & Feasibility (qualifications, training, time on site, length visit, location)
- Regulatory submission (complexity & timing for approval)
- Recruitment & Set-up (EDC & CRFs)
- Vendors & Study Equipment

11

Definition of the W6

- Who: Who is completing the related task and who is involved.
- What: The ask of the protocol – i.e. study assessments/procedures, what data they're collecting, end points, etc.
- When: Timing
- Where: Location of study assessments
- Why: Study endpoints
- How: Day-to-day logistics

12

Who

The "who" refers to all individuals and entities involved in the study.

Key Questions to Consider:

- Who are the study participants? (inclusion/exclusion criteria)
- Who will conduct the study? (researchers, investigators, coordinators)
- Who are the stakeholders? (sponsors, regulatory bodies, ethics committees)
- Who is responsible for data collection, analysis, and monitoring?

Importance: Understanding "who" helps ensure proper recruitment, roles, and responsibilities, contributing to the ethical and operational success of the trial.

13

What

The "what" defines the core elements and objectives of a clinical trial.

Key Questions to Consider:

- What is the intervention or treatment being tested?
- What are the research questions or hypotheses?
- What outcomes are being measured? (primary and secondary endpoints
- What procedures, assessments, or tests will be done?

Importance: Defining "what" ensures clarity on the study's scope, methods, and goals, guiding both execution and evaluation.

14

When

The "when" establishes the timeline and critical milestones of the study.

Key Questions to Consider:

- When will the study start and end?
- When will participants be enrolled, and what are the timelines for visits or assessments?
- When will data be collected and analyzed?

Importance: Understanding "when" helps in scheduling, resource allocation, and monitoring of the study's progression, ensuring that timeframes are realistic and milestones are met.

15

Where

The "where" addresses the physical and logistical aspects of conducting the trial.

Key Questions to Consider:

- Where will the study be conducted? (clinic, hospital, dedicated research space)
- Where will data be stored? (databases, paper or electronic documentation)
- Where will participants be recruited from? (site's own database, cold calling)

Importance: The "where" impacts recruitment strategies, regulatory compliance, and the availability of resources and support, which directly affects the feasibility and scalability of the trial.

16

Why

The "why" explains the rationale and purpose behind the study.

Key Questions to Consider:

- Why is this study being conducted? (scientific/medical need, filling knowledge gaps)
- Why is this intervention being tested? (mechanism of action, previous evidence)
- Why is this patient population chosen? (relevance, prevalence, safety considerations)

Importance: The "why" justifies the study's existence, guides decisions related to trial design, and ensures that the research is aligned with scientific and ethical standards.

17

How

The "how" outlines the methodology and processes by which the clinical trial will be carried out. It connects the theoretical framework of the protocol with the practical steps for implementation.

Key Questions to Consider:

- How will participants be recruited and screened for eligibility?
- How will data be collected? (paper vs. electronic source documentation)
- How will the study's integrity be maintained? (monitoring, quality control, data validation)
- How will safety and adverse events be managed? (protocol for reporting, response plans)

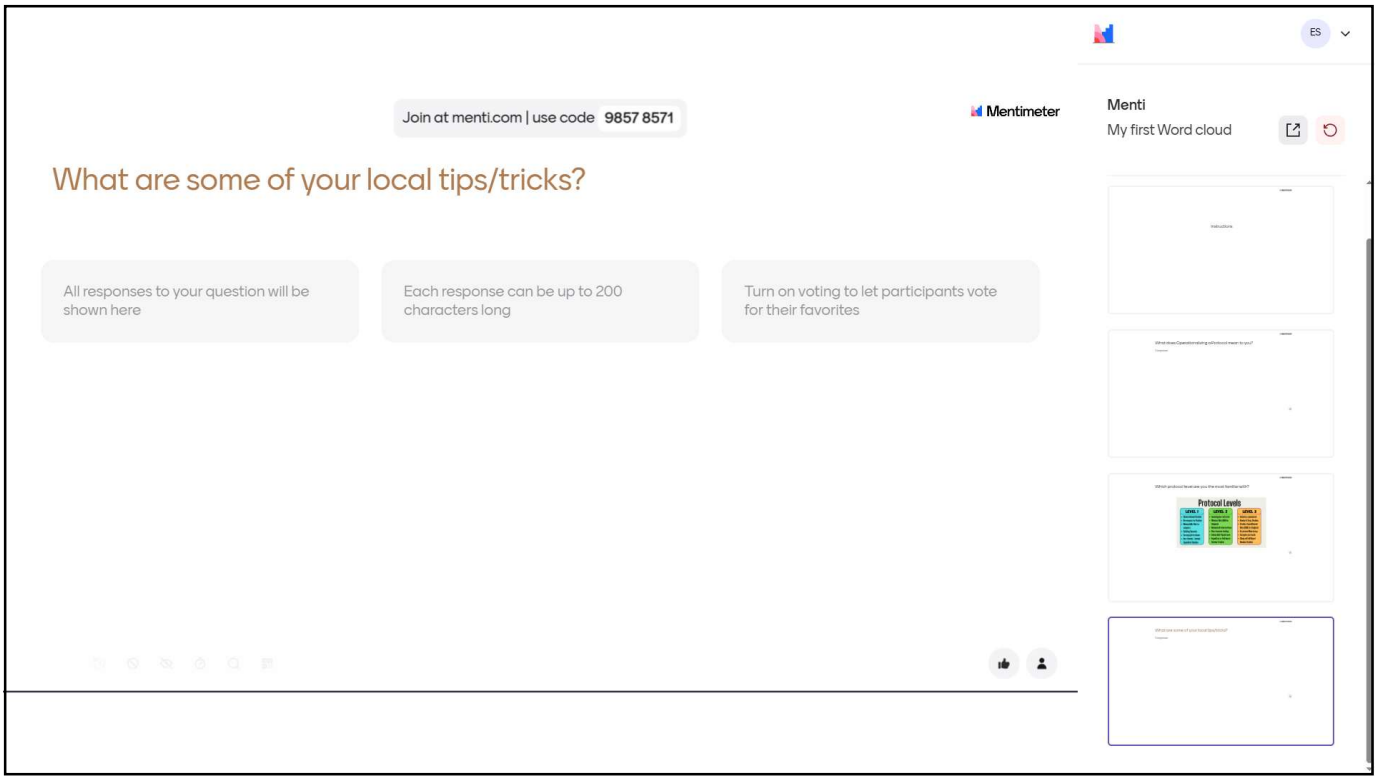
Importance: The "how" details the step-by-step actions required to execute the study, ensuring consistency, reliability, and compliance with the protocol. It serves as a roadmap for the trial team, helping to mitigate risks, ensure standardization, and guarantee reproducibility

18

Best Practice

- Checklists
  - After Initiation – ensuring everyone has access to all required systems
  - Visit checklists
- Communication
  - Recurring internal team meetings
- Training
  - Continuing education opportunities
- Quality Assurance
- Adaptability

19



20

Whiteboard

21

Study Title: Evaluation of Immune Response in Hospitalized Influenza Patients

Study Purpose:
This study aims to assess the immune response in patients hospitalized with influenza.

Study Design:
This is a prospective observational study. Hospitalized patients diagnosed with influenza will be enrolled upon obtaining informed consent. No experimental interventions will be performed, and the study will not alter the standard of care for participants.

Informed Consent:
Participants will be fully informed about the study procedures and will provide written informed consent prior to enrollment.

Expected Outcomes:
participant responses to questionnaires will help understand the clinical course and treatment effects in a hospitalized population.

Background information: The study PI is a hospitalist at a large academic institution. There is one coordinator, and one research assistant assigned to the study who are also involved in other studies with different PIs. The coordinator's offices are in another building on campus (within walking distance) and not in the main hospital.

Inclusion Criteria:

1. Participants must be 18 years of age or older.
2. Must have a confirmed diagnosis of influenza (by PCR) within 24 hours prior to hospitalization admission.
3. Participants must be hospitalized for treatment of influenza or its complications.

Exclusion Criteria:

1. Participants with a primary diagnosis of a non-influenza viral infection or bacterial pneumonia (i.e., not influenza-related) will be excluded, as the study focuses specifically on influenza-related immune responses.
2. Patients with severe comorbidities that are expected to impact the course of influenza or the ability to complete study activities

22

Key Takeaways

- Be proactive identifying and addressing challenges to ensure smooth study operations
- Operationalizing a protocol isn't a one-person job. Ensure open lines of communication and collaboration across all teams involved
- Be solution-oriented. When obstacles arise, analyze the issue and collaborate with your team and the sponsor to find the best path forward.
- Be flexible!

23